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(54) Title: SURGICAL/DIAGNOSTIC IMAGING DEVICE			
(57) Abstract			
<p>A surgical/diagnostic imaging device for use in interabdominal, interthoracic, and other surgical and diagnostic procedures includes an image sensor (180) pivotally mounted at the distal end of a support (178). In use, the image sensor (180) and support (178) are contained within a disposable sterile sheath (152), and the distal portion (202) of the sheath is inserted into the patient through an incision. The imaging device includes actuators (154, 158) to move the image sensor in elevation and azimuth.</p>			

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**Title: SURGICAL/DIAGNOSTIC IMAGING DEVICE****TECHNICAL FIELD OF THE INVENTION**

This invention is related to an imaging device for use in interabdominal, interthoracic, and other surgical and 5 diagnostic procedures on the human body.

**BACKGROUND**

Endoscopic surgery and diagnosis are considerably less invasive than the conventional procedures. This results in a 10 lower mortality rate and minimizes both the patient's hospital stay and recovery time.

Conventional endoscopes include a rigid elongated member, a lens assembly, and an imaging device mounted either on or within the endoscope. Examples of such endoscopes are 15 described in U.S. Patents Nos. 4,697,210 (Toyota et al.), 4,791,479 (Ogiu et al.), and 4,989,586 (Furukawa).

Although a conventional endoscope can be constructed to have a wide field of view, the picture quality suffers. As a practical matter, the field of view of conventional endoscopes 20 must be relatively narrow. As a result, a conventional endoscope must be positioned carefully at the beginning of a procedure, then held in position throughout the procedure, which generally requires the full-time attention of one member of the operating team. U.S. Patent No. 5,351,678 (Clayton et 25 al.) addresses the initial positioning problem by providing an endoscope having a distal end which is offset from the

endoscope's longitudinal axis. With the Clayton et al. endoscope, the surgeon can easily change the area viewed by rotating the endoscope about its longitudinal axis. However, the Clayton et al. endoscope must still be held in place throughout the procedure by a member of the operating team.

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#### SUMMARY OF THE INVENTION

A surgical/diagnostic imaging device embodying the invention includes a charge-coupled device ("CCD") and an associated lens mounted within a camera bore in a camera housing. The camera housing is pivotally mounted at the distal end of an elongated camera support. High intensity lights are also mounted within bores in the camera housing that are coaxial with the camera bore and thus with the axis of the CCD.

Prior to use, the camera housing and camera support tube are inserted into a disposable sterile sheath. The distal portion of the sheath is then inserted into the patient through an incision in the patient. Electric stepper motors and associated components are provided to move the camera housing (and thus the CCD) in elevation and azimuth.

The imaging device is electrically connected to a control console. The control console is in turn electrically connected to a display device and a control assembly. The display device displays the image received by the CCD and the control assembly allows the surgeon to control the elevation and azimuth of the camera housing.

The surgical/diagnostic imaging device is easily aimed at the area of interest within the patient by the surgeon. In addition, surgical/diagnostic imaging device need not be held in position in the patient by a member of the operating team.

**BRIEF DESCRIPTION OF THE DRAWINGS**

An embodiment of the invention will be described, by way of example only, with reference to the accompanying drawings, in which:

5 Fig. 1 is a front view of a surgical/diagnostic imaging device in accordance with the invention;

Fig. 2 is a partially cutaway side view of the imaging device of Fig. 1;

10 Fig. 3 is a cutaway top view of the sheath cap taken through plane 3-3 in Fig. 1;

Fig. 4 is an enlarged cutaway side view of the upper housing and the lower portion of the imaging device;

Fig. 5 is a cutaway top view of the upper housing taken through plane 5-5 in Fig. 4;

15 Fig. 6 is an cutaway top view of the lower portion of the imaging device taken through plane 6-6 in Fig. 4;

Fig. 7 is a block diagram of a system for controlling the imaging device of Fig. 1 and for displaying the images transmitted by the imaging device;

20 Fig. 8 is a block diagram of a second control and display system for the imaging device of Fig. 1;

Fig. 9 is a cutaway side view of a second imaging device in accordance with the invention;

25 Fig. 10 is a front view of the camera housing shown in Fig. 10; and

Fig. 11 is a cutaway side view of the camera housing taken through plane 11-11 in Fig. 10.

**DETAILED DESCRIPTION**

Figs. 1-3 show a surgical/diagnostic imaging device 1 for use in interabdominal, interthoracic, and other surgical and diagnostic procedures. The device 1 comprises an upper housing 3, a camera housing 5, and left and right camera housing supports 7, 9. Before use, the device 1 is inserted into a sterile sheath 11. The device 1 and sheath 11 (collectively, the "camera") are then inserted through an incision (not shown) into the patient's body (not shown). The camera is inserted so as place the camera housing 5 in a position from which it can be pointed at the surgical site or the area to be diagnosed. The incision is sealed around the camera with a purse string stitch, thereby preventing leakage of the CO<sub>2</sub> gas which is used to distend the patient's abdomen or chest during surgery or diagnosis.

15 In this embodiment, the sheath 11 is constructed of medical-grade plastic and is intended to be disposed of after use. Alternately, the sheath 11 can be constructed of heat-resistant materials in order to allow it to be sterilized using an autoclave, then reused.

20 The camera housing 5 contains a CCD (not shown) and a zoom lens assembly (not shown). A plurality of high intensity lights 13 are mounted within a light housing 15 which extends about the outer circumference of the camera housing 5. The lights 13 are aligned with the focal axis 17 of the CCD, and 25 they provide illumination of the area at which the camera housing 5 and hence the CCD are pointed.

When the device 1 is inserted in the sheath 11, the left and right camera housing supports 7, 9 engage complimentary locking keys 19, 21 within a sheath cap 23. As a result, the 30 camera housing 5 is locked into a position in which the CCD's

focal axis 17 is aligned perpendicular to an optically-clear window 25. In addition, as will be described below in connection with Figs. 4-6, the locking keys 19, 21 cause the sheath cap 13 to rotate about the longitudinal axis 27 of the 5 camera when the camera housing supports 7, 9 are rotated about that axis.

A camera cable 29 extends between the camera housing 5 and the upper housing 3. The camera cable 29 contains conductors which carry the CCD's signals to the upper housing 3 and which 10 supply electrical power to the CCD and lights 13. An imaging device cable 31 is provided to carry control signals and supply electrical power to the device 1 and to carry the CCD's signals to external processing and display devices (not shown).

The length of the camera housing supports 7, 9 and the 15 length of the sheath 11 are varied to accommodate variation in the thickness of the abdominal walls of patients and to allow the camera to be used in thoracic surgery/diagnosis. Three lengths are provided: 3, 6, and 11 inches below the upper housing 3.

20 Referring now to Figs. 4-6, an elevation motor 51 drives an elevation shaft 53 by means of gears 55, 57. The elevation shaft 53 extends downwardly through the hollow left camera support 7. A ring and pinon gear arrangement 59 at the lower end of the elevation shaft 53 transfers the rotary motion of 25 the elevation shaft 53 to the camera housing 15, thereby causing the camera housing 15 to elevate or depress, depending on the direction of rotation of the elevation motor 51. In this embodiment of the invention, the camera housing 15 can be elevated 70 degrees above horizontal and depressed 90 degrees 30 below horizontal.

The elevation motor 51 is mounted on a plate 63. The plate 63 is rotably mounted within the upper housing 3 on a bearing 65. An azimuth motor 67 is also mounted on the plate 63. The azimuth motor 67 drives an azimuth gear 69. The 5 azimuth gear 69 engages a housing gear 71 which is attached to the inner surface of the upper housing 3. When the azimuth motor 67 rotates, the plate 63 rotates within the upper housing 3. In this embodiment, the plate 63 rotates plus or minus 180 degrees in order to minimize the amount the camera cable 21 is 10 twisted. 360 degree rotation can easily be achieved by using conventional slip rings.

A zoom/focus motor 72 drives gears 73, 75, which rotate a zoom/focus shaft 77. The zoom/focus shaft extends downwardly through the right camera support 9. At the bottom of the focus 15 shaft 77, a ring and pinon arrangement 79 transfers the rotary motion of the focus shaft 77 to a zoom lens mechanism (not shown) within the camera housing 5.

Referring now to Fig. 7, the imaging device 1 is connected to a control console 101 by means of the imaging device cable 20 31. Signals from the CCD of the imaging device 1 are amplified by circuits in the control console 101 and directed to a display device 103. In this embodiment of the invention, the display device 103 is a conventional television set.

A foot pedal control assembly 105 allows the surgeon (not 25 shown) to control the imaging device 1. The foot pedal control assembly 105 includes four controls (not shown): (1) camera housing left and right; (2) camera housing up and down; (3) zoom in and out; and (4) light intensity up and down. Signals from the foot pedal control assembly 105 are routed to the 30 control console 101. Circuits (not shown) in the control

console 103 convert the control assembly signals into signals which are suitable to control the imaging device 1, then route the converted signals to the imaging device 1.

In the embodiment of the invention shown in Fig. 8, a 5 computer 107 is interposed between the control console 101 and the display device 103. A plurality of computer programs contained in the computer 107 allow operating team personnel to manipulate and/or store the signals from the imaging device 1.

10 Figs. 9-11 illustrate a second surgical/diagnostic imaging device in accordance with the invention. Referring first to Fig. 10, the imaging device comprises two major assemblies: a camera assembly 150 and a disposable sheath assembly 152.

In the camera assembly 150, a rotary stepper motor 154 is 15 rigidly mounted in an upper housing 156. A linear stepper motor 158 and the distal end of a planetary gear assembly 162 are press fitted in a linear stepper motor housing 164. The proximal end of the planetary gear assembly 162 is attached to the upper housing 156 by screws 168.

20 Three planetary gears 170 (only two of which are shown in Fig. 9) are rotably mounted on pins 172 within the planetary gear assembly 162. The rotary stepper motor 154 drives the planetary gears 170 through a sun gear 174.

The proximal end of a camera support tube 178 is press 25 fitted in the linear stepper housing 164. A camera housing 180 is pivotally mounted between pair of arms 182 (only one of which is shown in Fig. 9) that are integral with and extend from the distal end of the camera support tube 178. The linear stepper motor 158 acts through a pushrod 186 and a fork 188 to 30 control the elevation of the camera housing 180.

The disposable sheath assembly 152 comprises a sheath 190, a sheath housing 192, and a ring gear 194. The distal portion of the sheath 190 is optically clear. The proximal end of the sheath 190 is adhesively attached within the distal end of the 5 sheath housing 192. The ring gear 194 is adhesively attached within the proximal end of the sheath housing 192.

Prior to use, the camera assembly 150 is inserted into the sheath assembly 152, and the planet gears 170 engage the ring gear. As a result, when the rotary stepper motor 154 is 10 actuated, the camera assembly 150 rotates in relation to the longitudinal axis 202 of the sheath assembly .

As is best shown in Figs. 10 and 11, a CCD assembly 204 and a lens 206 are mounted within a camera bore 208 in the camera housing 180. A pair of high intensity lights 210 are 15 mounted in bores that are coaxial with the camera bore 208.

A multi-conductor flexcable 212 provides the necessary connections for the CCD assembly 204, for the camera housing lights 210, and for three high intensity lights 214 that are disposed in bores in the pushrod 186. The flexcable 212 extends 20 from the camera housing 180 to the upper housing 156. In the upper housing 156, the flexcable 212 is combined with power and control wires (not shown) for the rotary stepper motor 154 and the linear stepper motor 158 to form the camera assembly cable 218. The camera assembly cable 218 passes through an orifice 25 220 in the upper housing 152. As with the embodiment of the invention shown in Figs. 1-8, the camera assembly cable 218 connects the camera assembly 150 to external display and control devices (not shown).

**CLAIMS**

1. An surgical/diagnostic imaging device comprising:  
an image sensor pivotally connected adjacent to the distal  
end of an elongated support; and  
a first actuator connected to the image sensor, which  
actuator is adapted to pivot the image sensor relative to the  
support.
2. The imaging device of claim 1 wherein the first  
actuator is adapted to pivot the image sensor in a plane  
parallel to the longitudinal axis of the support.
3. The imaging device of claim 2 wherein the actuator is  
connected to the image sensor by a gear and shaft assembly.
4. The imaging device of claim 2 further comprising a  
second actuator for rotating the support about the longitudinal  
axis thereof.
5. The imaging device of claim 1 further comprising  
display means connected to the image sensor.
6. The imaging device of claim 2 further comprising an  
elevation controller connected to the first actuator.
7. The imaging device of claim 4 further comprising an  
azimuth controller connected to the second actuator.

8. The imaging device of claim 1 further comprising light means disposed adjacent to the image sensor and substantially coaxial therewith.

9. The imaging device of claim 2 further comprising an elongated sheath disposed about the support and image sensor.

10. The imaging device of claim 9 further comprising a second actuator for rotating the support within the sheath.

11. The imaging device of claim 1 further comprising a lens disposed adjacent to the image sensor.

12. The imaging device of claim 11 wherein the lens is movable relative to the image sensor, the imaging device further comprising a focus actuator connected to the lens.

13. An surgical/diagnostic imaging device comprising:  
image sensing means pivotally connected adjacent to the distal end of an elongated support; and  
elevation means for pivoting the image sensing means in a plane parallel to the longitudinal axis of the support.

14. The imaging device of claim 11 further comprising means for rotating the support about the longitudinal axis thereof.

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Fig. 1

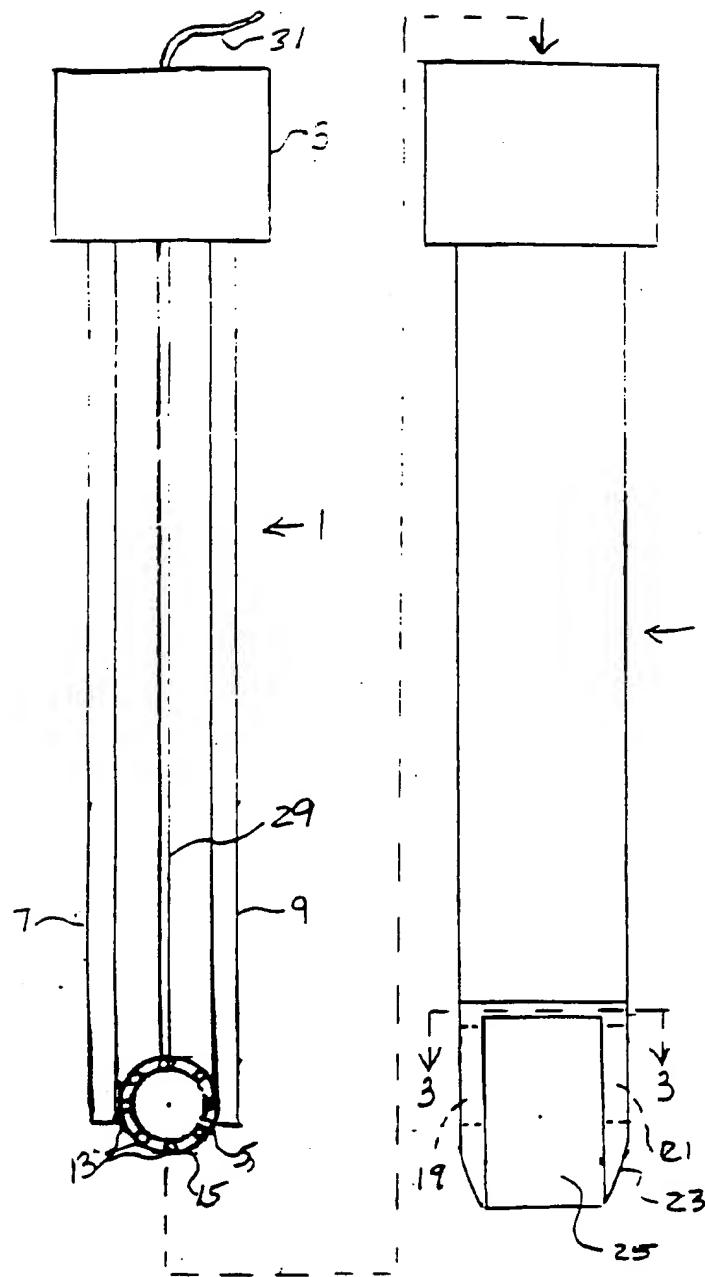


Fig. 2

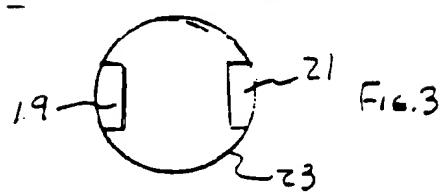
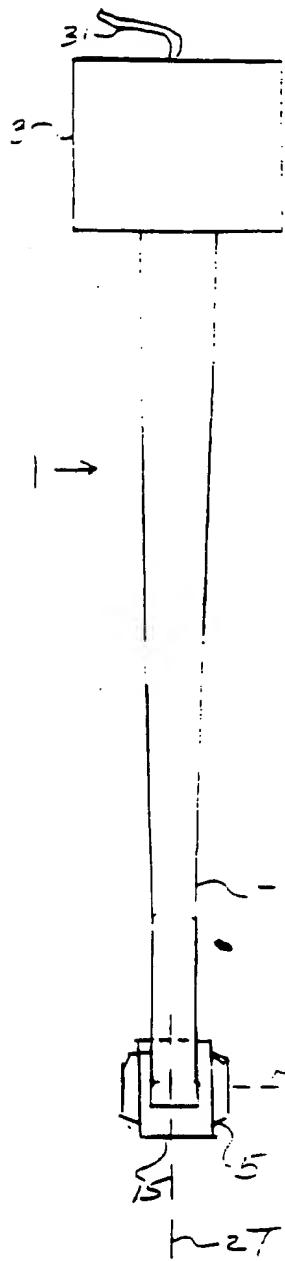
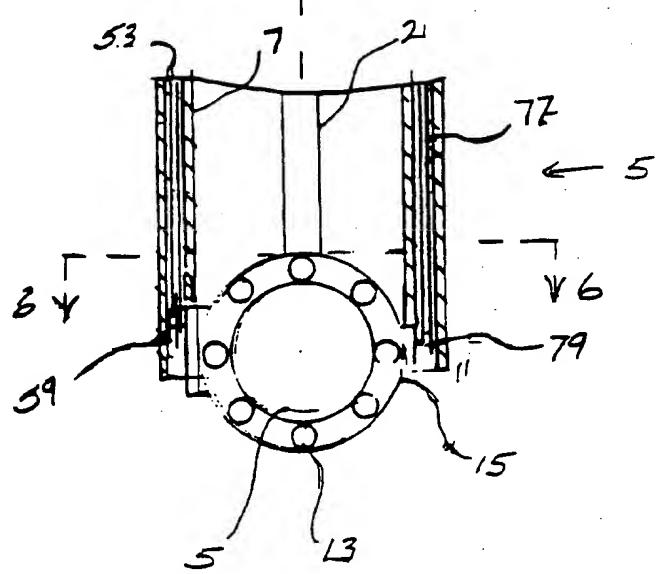
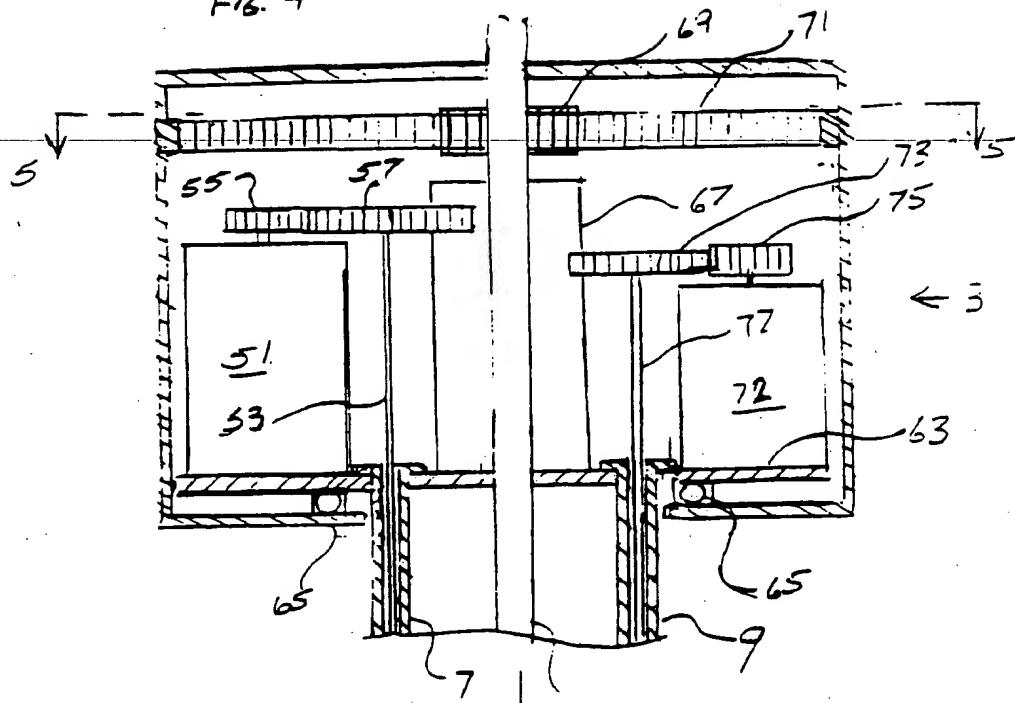


Fig. 3

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Fig. 4



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FIG. 5

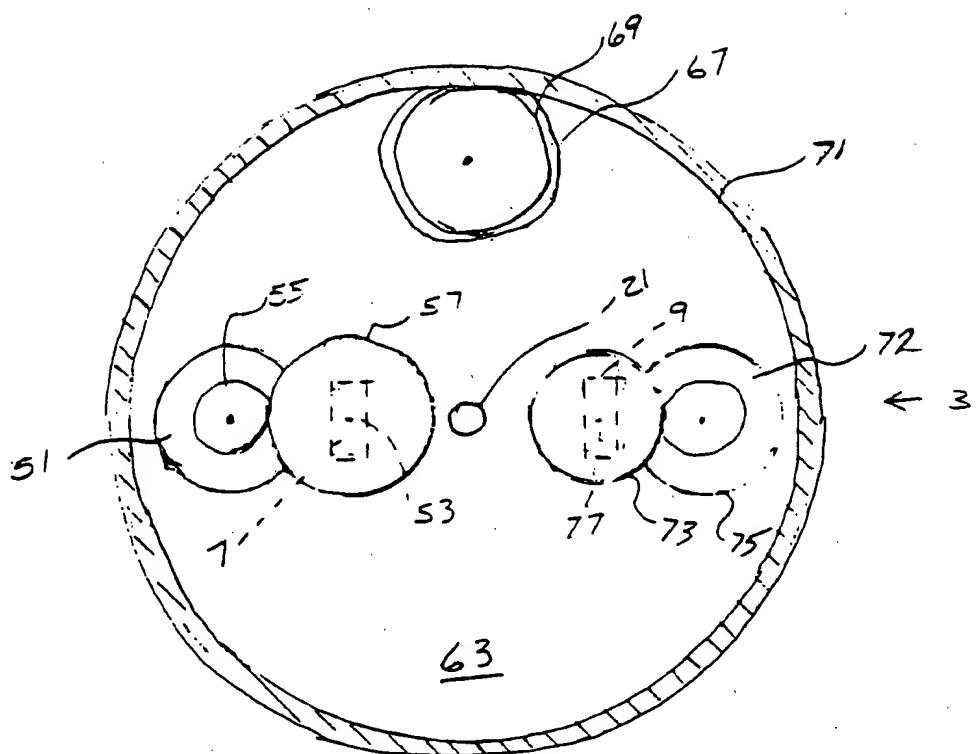


FIG. 6

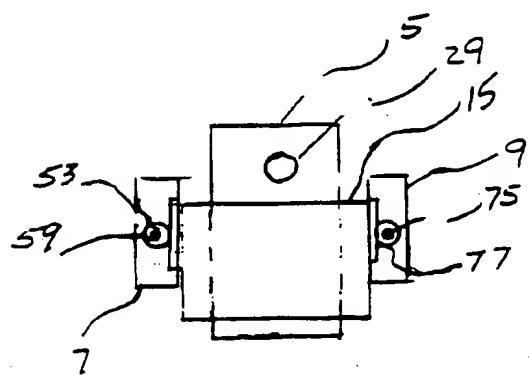


FIG. 7

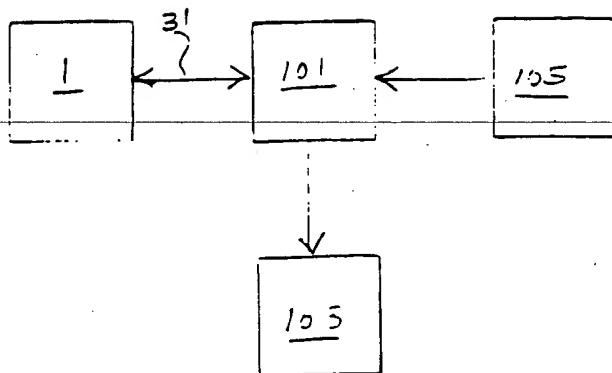
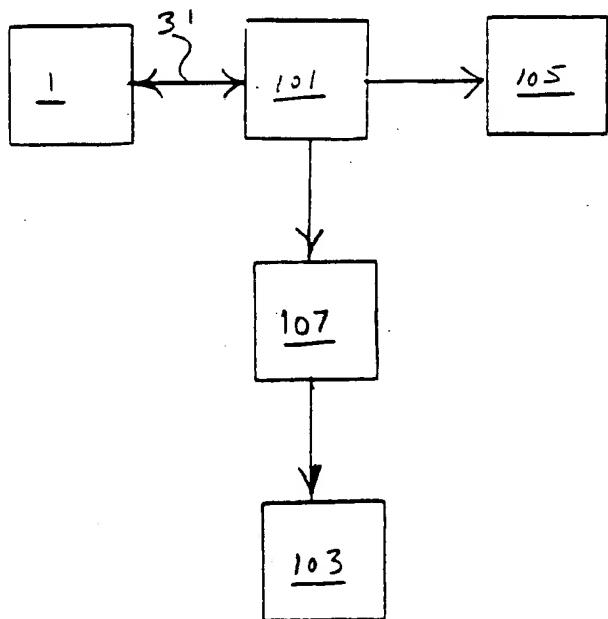


FIG. 8



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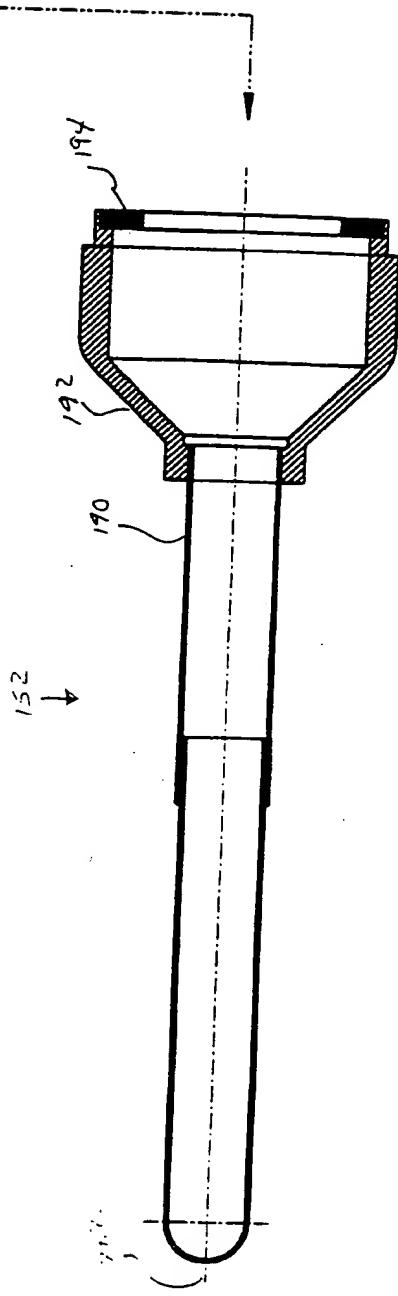
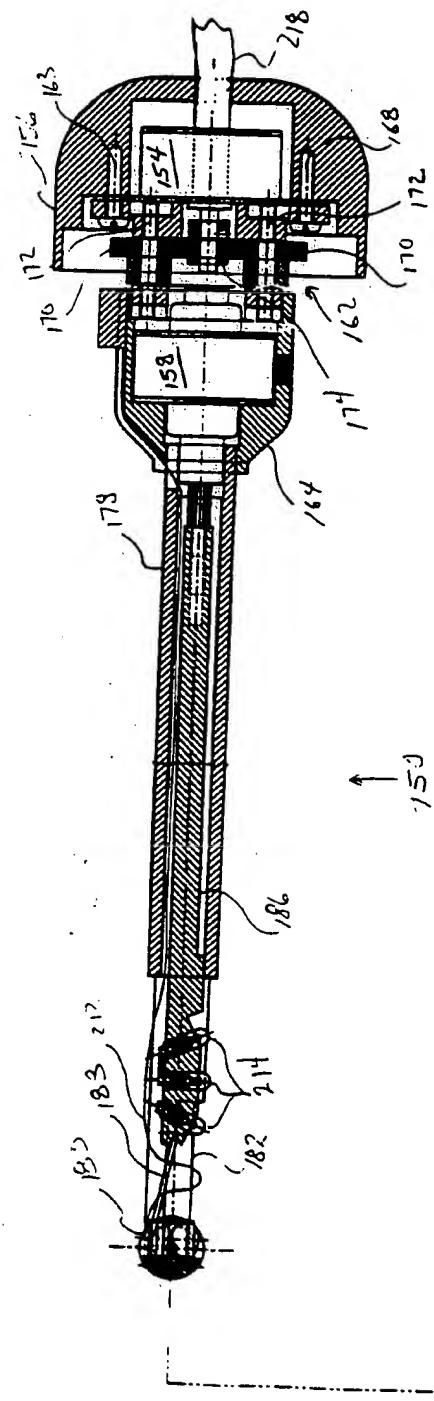


FIG. 9

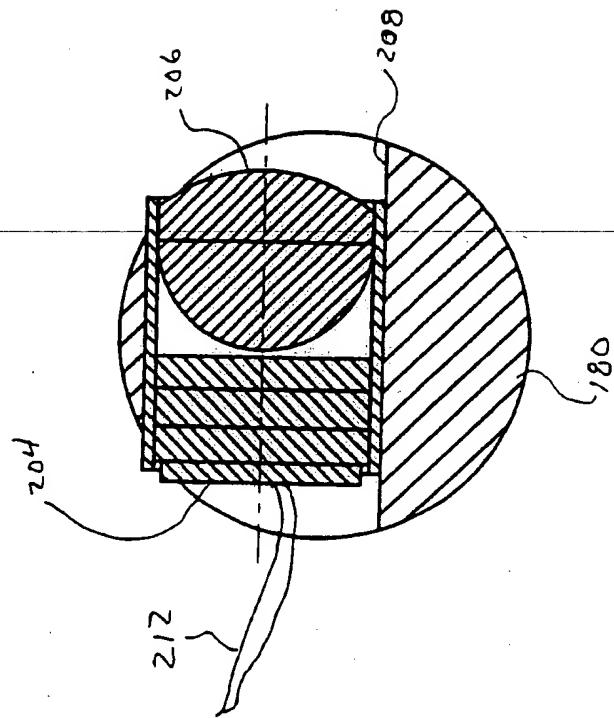


Fig. 11

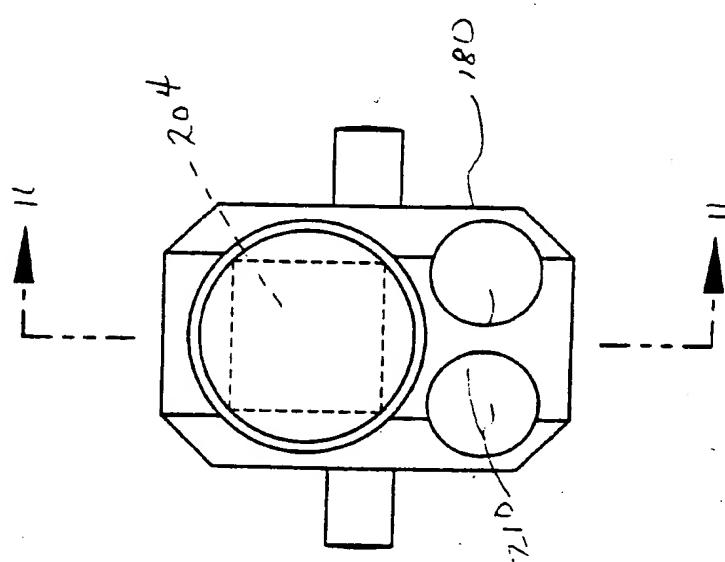


Fig. 10

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US96/14921

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) A61B 1/04  
US CL 348/65; 600/112, 173

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/112, 173; 348/65

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
none

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
none

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,028,997 A (ELBERBAUM) 02 July 1991, entire disclosure.	1, 2, 4-7, 9-11, 13, 14
X,P	US 5,508,735 A (MUELLER) 16 April 1996, entire document.	1-8, 11, 13, 14
X	US 5,305,121 A (MOLL) 19 April 1994, entire document.	1, 2, 4-9, 11, 13, 14
X	US 4,855,838 A (JONES et al.) 08 August 1989, entire document.	1-3, 5, 6, 9, 11-13
X	US 5,381,784 A (ADAIR) 17 January 1995, entire document.	1, 2, 5, 6, 11-14

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document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

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Date of the actual completion of the international search

30 JANUARY 1997

Date of mailing of the international search report

03 MAR 1997

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International application No.  
PCT/US96/14921

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,111,288 A (BLACKSHEAR) 05 May 1992, entire document.	1-7, 9-14
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Y		12